Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jul 2026

Investigating the effect of Quetiapine on delirium in patients undergoing coronary artery bypass graft surgery; a double-blind clinical trial

Protocol summary

Study aim

Investigating the effect of quetiapine on delirium in patients undergoing CABG surgery

Design

A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial of 82 patients. For randomization, a random sequence created in blocks of four using the site http://www.graphpad. com/quickcalcs/index.cfm will be used.

Settings and conduct

This study will be conducted as a clinical trial in Heshmat Hospital in Rasht. After explaining the purpose and method of the research, informed consent will be obtained. Patients will be randomly divided into intervention and control groups. The medicine will be given to the patient by a nurse who is not in the study. The drug will be administered orally or through a nasogastric/intestinal tube. Delirium examination of patients in the ICU will be evaluated by a trained anesthesiologist on a daily basis, from the day of surgery until the patient's discharge from the ICU. The delirium assessment criteria will be the CAM-ICU scale (Confusion Assessment Method for the ICU). This study will be double-blinded. The patient and the evaluator (anesthetist assistant) will be unaware of the treatment groups. The anesthesiologist of the ICU team is aware of the groups so that in case of complications, therapeutic interventions can be performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Elective patients , 35-85 years, ASA Class II,III, GCS 15. Exclusion criteria: liver and kidney failure, history of mental illness and cognitive behavioral problems.

Intervention groups

Intervention group:12.5 mg of oral quetiapine , the first dose on the morning of surgery, before surgery (quetiapine 25 mg tablet), and then every 12 hours until 48 hours after surgery, for a total of 4 doses. Control group: will not receive any drug prophylaxis.

Main outcome variables

Occurrence of delirium during ICU hospitalization

General information

Reason for update

1- Editing information related to Inclusion criteria(GCS 15, ASA Class II,III): GCS 15 is appropriate because the assessment of postoperative delirium in patients entering the study must be clinically fully conscious. ASA Class II,III is appropriate because ASA Class IV is for patients undergoing emergency surgery, but this study was conducted in patients who were candidates for elective coronary artery bypass grafting. 2- In the intervention section, the method of administering quetiapine was described in more detail and revised. Also, the time period for examining delirium in postoperative patients was revised to 3 days after surgery, as patients are hospitalized in the ICU for a maximum of three days after surgery.

Acronym

IRCT registration information

IRCT registration number: **IRCT20130525013456N7**
Registration date: **2023-08-21, 1402/05/30**
Registration timing: **prospective**

Last update: **2025-09-25, 1404/07/03**
Update count: **2**

Registration date

2023-08-21, 1402/05/30

Registrant information

Name

Abbas Sedighinejad

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 911 132 5712

Email address
a_sedighinejad@gums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-08-23, 1402/06/01
Expected recruitment end date
2024-03-20, 1403/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of Quetiapine on delirium in patients undergoing coronary artery bypass graft surgery; a double-blind clinical trial

Public title
effect of Quetiapine on delirium in patients undergoing coronary artery bypass graft surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Elective patients who are candidates for coronary artery bypass surgery 85- 35 years American Society of Anesthesiologists (ASA) II,III GCS 15 to be fully alert and able to communicate
Exclusion criteria:
Liver and kidney failure Emergency surgery Confirmation of delirium before ICU admission Patients with a history of mental illness and cognitive behavioral problems before surgery Allergy to quetiapine and its ingredients
Age
From **35 years** old to **85 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **82**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be assigned to two groups: quetiapine and control by a random sequence created in blocks of four by using the site http://www.graphpad.com/quickcalcs/index.cfm, which was created by a statistical consultant in a ratio of 1:1 and will be performed by a nurse who is not aware of the goals of the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this double-blind study, the drug will be given to the patient by a nurse who is not participating in the study, and the delirium of patients in the ICU will be evaluated and recorded by a trained anesthesia assistant who is unaware of the treatment groups. In this way, the patient and the person evaluating and recording the information (trained anesthesia assistant) will be unaware of the treatment groups. The anesthesiologist of the ICU team will be aware of the groups to take the necessary actions in case of complications.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street,Rasht
City
Rasht
Province
Guilan
Postal code
4144654839
Approval date
2023-07-26, 1402/05/04
Ethics committee reference number
IR.GUMS.REC.1402.242

Health conditions studied

1

Description of health condition studied
Determining the effect of Quetiapine on delirium in patients undergoing CABG surgery
ICD-10 code
F05.8
ICD-10 code description
Postoperative delirium

Primary outcomes

1

Description
Occurrence of delirium during ICU hospitalization

Timepoint
Daily from the day of surgery until the patient is discharged from the ICU (for 3 days)
Method of measurement
CAM- ICU (Confusion Assessment Method for the ICU)

Secondary outcomes

1

Description
Side effects of the drug
Timepoint
Daily
Method of measurement
Observation

Intervention groups

1

Description
Intervention group: The group will receive 12.5 mg of oral quetiapine, the first dose on the morning of surgery, then every 12 hours until 48 hours after surgery (25 mg quetiapine tablets manufactured by Fatek Shimi Pars Company - Iran), for a total of 4 doses, by a nurse who is not in the study. In patients with a nasogastric/intestinal tube, the patient's dose of quetiapine will be crushed, mixed with 10 ml of water and administered through the nasogastric/intestinal tube. The feeding tubes will be flushed with 30 ml of sterile water after each dose of quetiapine according to hospital protocol.
Category
Prevention

2

Description
Control group: The control group will not have any medical prophylaxis.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Heshmat Hospital
Full name of responsible person
Abbas Sedighinejad
Street address
Fifteenth Khordad Street
City
Rasht
Province
Guilan
Postal code
4165432678
Phone
+98 911 132 5712
Email
heshmat@gums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Dr Mohammadreza Naghipoor
Street address
Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street,Rasht
City
Rasht
Province
Guilan
Postal code
6694941446
Phone
+98 13 3333 5821
Email
naghi@gums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Abbas Sedighinejad
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Anesthesiology Research Center, Alzahra Hospital, Namjoo Street, Rasht, Iran

City
Rasht
Province
Guilan
Postal code
4144654839
Phone
+98 13 3332 9524
Fax
+98 13 1323 3448
Email
A_sedighinejad@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Abbas Sedighinejad
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Anesthesiology Research Center, Alzahra Hospital, Namjoo Street, Rasht, Iran
City
Rasht
Province
Guilan
Postal code
4144654839
Phone
+98 13 3332 9524
Fax
+98 13 1323 3448
Email
A_sedighinejad@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mohadese Ahmadi
Position
Research Expert/(MSc) English
Latest degree
Master
Other areas of specialty/work
Research Expert
Street address
Anestesiology Reseaech Center, Alzahra Hospital, Namjoo Street
City
Rasht
Province
Guilan
Postal code
4144654839
Phone
+98 13 3336 9328
Email
p.ahmadi2311@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available